REMARKS

Claims 28, 31-44, 48, 50, 57 and 58 are currently pending in this application. Claims 1-27, 29, 30, 45-47, 49, 51-56 and 59-61 were previously cancelled without prejudice or disclaimer as to the subject matter contained therein. Applicants respectfully reserve the right to prosecute the subject matter of the cancelled claims in one or more continuation or divisional patent applications.

Rejections

Rejections under 35 U.S.C. § 112, 1st paragraph

Written Description

Claims 28, 31-44, 48, 50, 57 and 58 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking written description. The Office Action states that the recitations of "symptoms associated therewith in a woman" as well as "wherein the woman has breast cancer, has had breast cancer, or has a risk of developing breast cancer" is considered new matter. The Office Action requested a showing of support in the disclosure

Applicants respectfully disagree and traverse this rejection.

Applicants submit that the claims are fully supported by the specification as originally filed. Applicants submit that the recitation of "symptoms associated therewith in a woman," when read in proper context in the claim following the recitation of "treating estrogen deficiency in a woman," finds support throughout the application as originally filed, *inter alia*, on page 2, line 32 extending to page 3, line 2. A listing of estrogen deficiency-conditioned symptoms is located on page 10, line 33 extending to page 11, line 8.

Applicants submit that the recitation of "wherein the woman has breast cancer, has had breast cancer, or has a risk of developing breast cancer" finds support throughout the application as originally filed, *inter alia*, on page 9, line 28 extending to page 10, line 2; page 10, lines 13-21; and Examples 7, 8 and 9.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 28, 31-44, 48, 50, 57 and 58 under 35 U.S.C. § 112, 1st paragraph, as allegedly containing new matter.

Enablement

Claims 28, 31-44, 48, 50, 57 and 58 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly lacking enablement for the method for treating an estrogen deficient woman that has a risk for developing breast cancer.

Applicants respectfully disagree and traverse this rejection.

The Office Action sets forth eight (8) factors to be considered in determining whether a disclosure meets the enablement requirement, as articulated in *In re Wands*. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). It is well established under 35 U.S.C. §112 ¶ 1, that "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986)). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), MPEP § 2164.01. As noted in the Office Action, the factors to be considered in determining whether a disclosure would require undue experimentation include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims." *In re Wands, supra.*

Applicants respectfully submit that the claimed subject matter is enabled by the specification as originally filed. The claims require that the woman has breast cancer, has had breast cancer, or has a risk of developing breast cancer. Applicants submit that undue experimentation is not required to ascertain which women have breast cancer or have had breast cancer. Similarly, Applicants submit that undue experimentation is not required to determine which women are at risk for developing breast cancer. For example, a strong genetic predisposition factor is believed to be involved with the development of breast cancer. Through their family doctor or based on family history, women may determine whether they are at risk for developing breast cancer. The specification, on page 9, lines 32-33 states that risk and high risk groups can be identified by statistical population studies.

Applicants also submit that the skilled artisan is familiar with *Cimicifuga racemosa*, and is capable of obtaining the same. Applicants further submit that ample guidance is provided by the teachings of the specification as originally filed for obtaining extracts of *Cimicifuga racemosa* for administration to a woman in accordance with the claims.

Applicants also note that the specification as a whole, including example 1, on page 15, line 23 extending to page 16, line 6, provides detailed guidance enabling one skilled in the art to produce aqueous *Cimicifuga racemosa* extract compositions used in the claimed methods. In particular, example 1 teaches that a standardized *Cimicifuga racemosa* material as for example provided by Finzelberg AG, Germany (catalogue number 0472312 or 0472340) was used for extraction purposes. The desired extraction solution was made from 100 mgs of *Cimicifuga racemosa* material and 1660 ml of sterile water, which was vortexed and then kept at room temperature for 30 minutes.

The specification also provides guidelines for dosing concentrations of *Cimicifuga racemosa* extracts. For example, the specification on page 3, lines 22-29, states that doses of the extract may be from, e.g., 1 mg to 20 mg daily on the basis of the extract, such as 2-3 mg twice daily for a woman. Example 1 also provides dosing amounts used in the murine models of the specification.

Based at least on these portions of their disclosure, Applicants submit that the teachings of the specification enable one skilled in the art to practice the claimed invention without undue experimentation. For example, the specification provides adequate teachings enabling one skilled in the art to isolate *Cimicifuga racemosa* extracts. Additionally, the specification provides dosing guidelines for concentrations of *Cimicifuga racemosa* administered to patients. As described *supra*, determinations of a woman's risk of breast cancer, or a determination of the presence of breast cancer or prior diagnoses of breast cancer, do not require undue experimentation. Applicants submit that these teachings are more than adequate to enable one skilled in the art to obtain *Cimicifuga racemosa* extracts and utilize those extracts in the claimed methods of the invention, without engaging in undue experimentation.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 28, 31-44, 48, 50, 57 and 58 under 35 U.S.C. § 112, 1st paragraph, as allegedly containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Rejections under 35 U.S.C. § 102

Claims 28 was rejected under 35 U.S.C. § 102(b), as allegedly anticipated by the disclosure of Nesselhut *et al* (U.S. Patent No. 6,267,994).

Applicants respectfully disagree and traverse this rejection.

As an initial matter, Applicants respectfully submit and reiterate from their prior response that Nesselhut *et al* is not a proper reference under 35 U.S.C. 102(b), because the instant application was filed less than one year after the publication date of Nesselhut *et al.*

In order for a reference to anticipate a claim, each and every element as set forth in the claim must be present, either expressly or inherently, in the cited prior art reference. Applicants respectfully submit that Nesselhut *et al* do not teach all of the elements of claim 28. Claim 28 is directed to the treatment of estrogen deficiency in a woman, and symptoms associated therewith, wherein the woman has breast cancer, has had breast cancer, or has a risk of developing breast cancer. Applicants submit that Nesselhut *et al* is not directed to the treatment of estrogen deficiency, and symptoms associated therewith, in a woman. Instead, Applicants submit that the disclosure of Nesselhut *et al* is directed to the treatment of estrogen-dependent cancer using compositions comprising *Cimicifuga* extracts, alone or in combination with at least one anti-estrogenic compound. Breast cancer is not a symptom of estrogen deficiency. Accordingly, since all of the elements of claim 28 are not taught by the disclosure of Nesselhut *et al*, Applicants submit that Nesselhut *et al* do not anticipate the subject matter of claim 28. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 28 under 35 U.S.C. § 102.

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants

would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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By: _____
Robin L. Teskin
Registration No. 35,030

Robert C. Lampe III
Registration No. 51,914

HUNTON & WILLIAMS LLP
1900 K Street, N.W.
Suite 1200
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201